Neurostimulators

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Neurostimulators

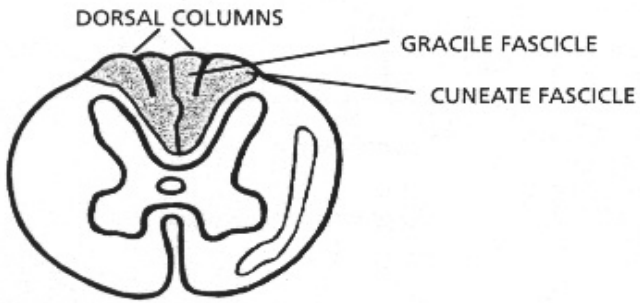
Neurostimulation is the stimulation of the neural tissues by tiny electrical impulses. These impulses block the transmission of pain messages to one's brain. Patients may feel a mild tingling sensation instead of pain.

APPROVED and FUTURE Neurostimulation Applications

Essential Tremor
Parkinson's
Dystonia
OCD: Obsessive-Compulsive Disorder
Depression
Tinnitus
Epilepsy
Stroke
Chronic Pain
Respiratory Support
Obesity
Gastroparesis
Irritable Bowel Syndrome
Profound Deafness
Headaches
TBI: Traumatic Brain Injury
Epilepsy
Depression
Angina Pain
PVD Pain: Peripheral Vascular Disease Pain
Incontinence
Pelvic Pain
Sexual Dysfunction

Example: Spinal Chord Stimulation (SCS)

- Last resort for pain treatment.
- Delivery of low intensity electrical pulses to the dorsal column to modify or block pain signals.
- Pain is replaced by a “tingling” sensation.



- Stimulation signals: AC voltage spike trains.
- Single frequency trains and envelopes are usually employed. Multiple frequencies are feasible.
- Single voltage spike: about 100 μs, 1-5 V.

Example: Spinal Chord Stimulation (SCS)

Catheters and electrodes:

- Cylindrical shape catheters with diameters of 1.2–3 mm.
- Flat catheters with 2–4 mm thickness.
- Each catheter with 2–16 independently addressable electrodes.
- Steerable with contourable shapes.

Implantable pulse generators: size, shape, similar to cardiac pacemakers.

Power source

- External RF-stimulation.
- Extended-life internal battery.
- Rechargeable internal battery.

Implant depths for rechargeable pulse generators:

- Less than 1 inch for all FDA-approved devices.
- Implant depths depend on antenna, case design, power required and operational variables.

Safety and Efficacy of Spinal Chord Stimulation for the Treatment Of Chronic Pain: A 20 Year Literature Review.

T. Cameron, J. Neurosurg (Spine 3) 100: 254-267, 2004.

68 studies, 5 indications

Back and leg pain

Complex regional pain syndrome

Ischemic limb pain

Angina pain

Miscellaneous pain

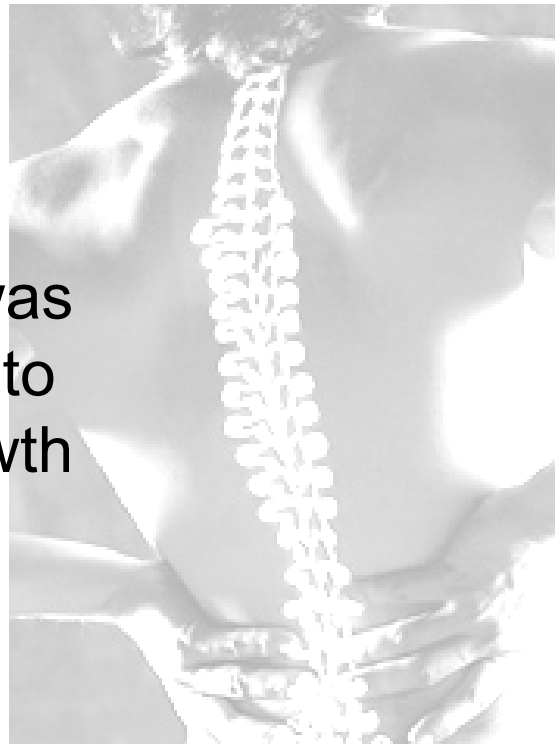
Examples

- 16 studies, 616 patients
- Follow-up period: 6 months–5 years
- Pain outcome: 56% to 88% reduction in pain following spinal cord stimulation
- 52% patients reported reduction or discontinuation of narcotic consumption

- 12 studies, 260 patients
- Follow-up period: 6 months–5 years
- Pain outcome: 57% to 100% reduction in pain following spinal cord stimulation
- 80% patients reported reduction or discontinuation of narcotic consumption

Market Size – Chronic Pain Management

Business Communications Company, Inc.:
The market for pain management, which comprises broadly of pharmaceuticals and devices, is at $18 billion in 2000. Growing at an AAGR (average annual growth rate) of 12% from 2000 to 2005, it is expected to reach $32 billion by 2005.



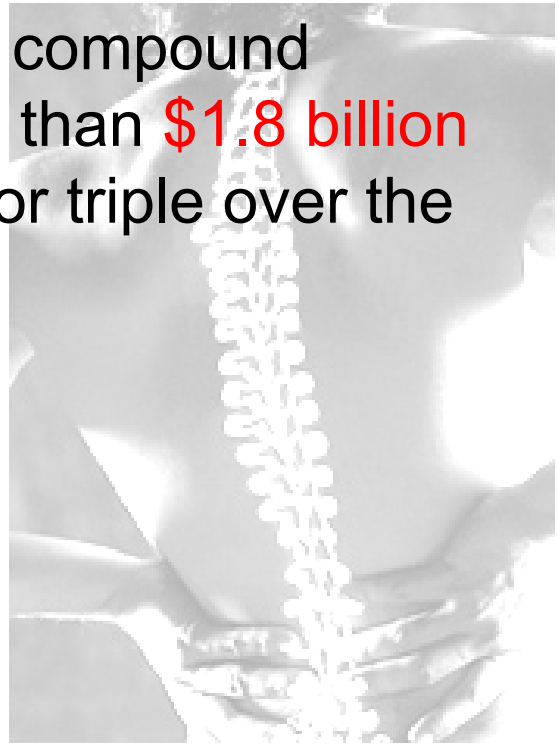
BioPortfolio:
The global pain management market was $21.6 billion in 2000 and it is expected to increase at a compounded annual growth rate of 4.7% to reach $29.7 billion in 2007.

Market Size – Neurostimulation

Medtech Insight 2006 November:

In 2005, the total U.S. market for neurostimulation products (including cochlear implants) was estimated at $830 million.

This market is expected to grow at a compound annual rate of 17.1%, reaching more than $1.8 billion in 2010, with the potential to double or triple over the next decade.



Technical Barriers

Multidisciplinary multi-institute research

Engineering
- Size
- Power consumption
- Power sources
- Features of stimulation
- Remote control (wireless)
- Operation/control difficulty
- Biocompatibility
- Surgical apparatus
- Design standards
- Design methodology

Clinical
- Procedures (time, surgery)
- Size
- Minimally invasive operation
- Surgical apparatus
- Measurement techniques
- Experiment methodology
- Side effects
- Long-term large-scale study
- Operation/procedure standards

Neuroscience
- Fundamental study
  – science of pain
- Modeling
- Optimization

Manufacturing
- Cost
- Size
- Reliability
- Characterization standards

Technical Barriers

Multidisciplinary multi-institute research

Engineering
- Size
- Power consumption
- Power sources
- Features of stimulation
- Remote control (wireless)
- Communication
- Biocompatibility
- Safety
- Durability

Clinical
- Procedures (time, surgery)
- Size
- Minimally invasive operation
- Surgical apparatus
- Measurement techniques

Education
- Medical school
- Nursing school
- Patient/public education
- Clinicians/General practitioners/Nurses/Administrators
- Insurance/Policy administrators

Neuroscience
- Fundamental study
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- Modeling
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Stage of Innovation Where Barrier Appears

Primary:Research
Secondary: Clinical

Measurement – Problem Part of the Barriers

Innovation in power source, wireless communication, size, safe electrodes, recorders, biocompatibility

Innovation in surgical apparatus, procedures, training, characterization

New applications

Potential Solutions to Measurement Problem

Innovation in power source, wireless communication, size, safe electrodes, recorders, biocompatibility

- Engineering research and development
- Neuroscience fundamental study
  - Government and industry funding

Innovation in surgical apparatus, procedures, training, characterization

- Neurosurgery/neurology/neurophysiology study
- Clinical participation
  - Government and hospital funding

New applications

- Academic/clinical collaboration
  - Government funding

Potential Providers of Solutions

Multidisciplinary nature of the problem, the solutions should be addressed by

- Academic laboratories
- Government laboratories
- Medical supplier companies
- Research hospitals
- Clinical hospitals
- Industrial laboratories

Potential Government Role

- Establish testbeds for characterization of biocompatibility, reliability, measurement definition and techniques, surgical procedures
- Define standards for researchers, users, manufacturers, regulators, service providers
- Define safety (e.g. EMI, battery) and policy of applications
- Education: users, manufacturers, regulators, service providers.
- Education: public (e.g. airport security).
- Sponsor fundamental research and long-term studies
- Coordinate multi-institute large-scale long-term clinical studies

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